

### **IN THE SPECIFICATION:**

The extraneous line on page 18 has been removed. A substitute sheet is attached .

At page 17, the current status of the copending application has been provided. Again a substitute sheet is attached.

### **REMARKS**

Applicant wishes to thank the Examiner for the careful consideration given this case. As examined, claims 1-45 were pending. Claims 1-9, 18-19, 29-30, and 41-45 were subjected to restriction as being drawn to a non-elected group. Accordingly those claims have been canceled by the present amendment. New claims 46-62 have been added. Thus, claims 10-17, 20-28, 31-40 and 46-62 are presented for further consideration in light of the remarks below.

### **THE EXAMINER'S ACTION**

In the Office Action mailed August 26, 2002, the Examiner made final the restriction requirement.

The Examiner also objected to the specification.

The Examiner also rejected claims 10-17, 20-28 and 31-40 under 35 U.S.C. 112, Second Paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner found the term "marker" in claims 10 and 20, as well as the term "indicator" in claims 10, 20 and 32 unclear.

### **REJECTIONS UNDER 35 U.S.C. § 112, Second Paragraph**

The marker as used in the claims is the entity being measured and compared against a reference value to determine the presence or absence of disease. As illustrated in Example 1, the value of the marker, which comprised

human IgG with a sTn epitope, was measured and compared to the reference value. To determine the value, or amount, of the marker, one may measure the bound detection reagent, which consists of an affinity ligand, which has affinity and specificity for sialocomplexes, and a detectable moiety bound to the sialocomplex. The language "if present" is to modify "an amount of detection reagent which is bound to the sample." If there is no detection reagent bound to the sample, then the lack of binding indicates the absence of sialocomplexes.

Indicator, as used in the claims, refers to markers meeting a condition. The condition may be comparing a reference value to the measured value of a marker. The comparison entails determining a difference between the two values, the difference (or similarity) can be obtained through subtraction or division, or any other method which would show a difference or lack thereof.

For improved clarity, attention is directed to the specification at page 15, line 27 through page 17, line 4.

The Examiner will appreciate that newly added claims 46-62 recite elements previously found allowable. Accordingly, entry and allowance are not believed to enter new matter or necessitate a new search.

**CONCLUSION**

In light of the remarks presented above, Applicant respectfully submits that the present application is in condition for allowance and notice to such effect is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees, or credit any overpayment, to Deposit Account No. 02-2051 identifying Attorney Docket No. 26983-50.

Respectfully submitted,

Dated: 11/25/02

By: W. Scott Harders

W. Scott Harders  
Reg. No. 42,629

BENESCH, FRIEDLANDER,  
COPLAN & ARONOFF LLP  
2300 BP Tower  
200 Public Square  
Cleveland, Ohio 44114  
(216) 363-4443